K002715

OCT 31 2000

510(k) SUMMARY

[As required by 21 CFR 807.87(h)]

Identification of Submitter

Submitter:	William Skremsky CTI PET Systems, Inc. 810 Innovation Drive Knoxville, TN 37932
Telephone No:	(865) 218-2522
Fax No:	(865) 218-3000
Date of preparation:	August 28, 2000

Identification of the Product

Device Proprietary Name:	ECAT PET/CT
Common Name:	Positron Emission Tomography (PET) Scanner
Classification Name:	Emission Computed Tomography System per 21 CFR 892.1200

Marketed Devices to Which Equivalence is Claimed

Device	Manufacturer	510(k) Number
ECAT EXACT HR+	CTI PET Systems (CPS)	K962797
SOMATOM Project 10 CT Scanner	Siemens Medical Systems	K991764

Device Description

The newly developed CPS/Siemens PET/CT system is a combined positron emission tomography and X-ray computed tomography scanner. This new tomograph utilizes major system components from both the currently marketed CPS ECAT EXACT HR+ (PET) and the Siemens Somatom Project 10 Emotion (CT) scanners within a unified housing to create an integrated, PET, CT, and combined PET/CT, tomographic imaging system.

The combined PET/CT scanner is intended for use primarily as a clinical, whole-body oncology machine with mid-range spiral CT performance and high-end PET performance. The CT component will also enhance PET scans by allowing fast, essentially noise-free attenuation correction for PET studies, and by providing precise anatomical reference through fused PET and CT images. In addition, the PET/CT system retains mechanical isolation and independent functionality of the PET and CT scanning systems, thereby allowing for most standard CT and PET clinical diagnostic protocols to be available on the PET/CT system.

The CT component of the PET/CT utilizes the Siemens SOMATOM Project 10 EMOTION, a whole body X-ray computed tomography scanner, which features a continuously rotating tube-detector system and functions according to the fan beam principle. Premarket notification for the Siemens SOMATOM EMOTION (originally named Project 10 Version B2) was submitted in 510(k) notification, K991764 and the system was cleared for commercial distribution in August of 1999.

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The PET component is a modified CPS ECAT EXACT HR+ PET scanner, a whole body positron emission tomography system providing 3D volume measurements of metabolic and physiologic processes, making available to the high end clinical research market a PET scanner having superior imaging resolution and count rate capability. Premarket notification for the CPS ECAT EXACT HR+ PET system was submitted in 510(k) notification, K962797 and the system was cleared for commercial distribution in October of 1996.

Indications for Use

The CPS/Siemens ECAT PET/CT system is a combined positron emission tomography (PET) and X-ray computed tomography (CT) scanner. The PET/CT scanner is intended to be utilized by appropriately trained health care professionals to 1) image and measure the distribution of injected positron emitting radiopharmaceuticals in humans for the purpose of determining various metabolic and physiologic functions within the human body; and 2) to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

The PET and the CT functions of this system can also be used in combination to provide high resolution, noise free CT attenuation correction maps for PET images and, additionally, utilized to produce fused CT and PET images, providing detailed anatomic and metabolic function information in a single image.

(*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube and the simultaneous translation of the patient.)

Comparison with Predicate Devices

This new tomograph utilizes major system components from both the currently marketed CPS ECAT EXACT HR+ (PET) and the Siemens Somatom Project 10 Emotion (CT) scanners within a unified housing to create an integrated, PET, CT, and combined PET/CT, tomographic imaging system.

The PET component of the new PET/CT scanner is similar in design and function to the ECAT EXACT HR+ PET scanner (K962797) with the elimination of the retractable septa and transmission sources. The patient port has been expanded from 56 cm to 70 cm to match the Somatom Emotion CT gantry aperture. The CT component of the PET/CT system is similar in design and function to Siemens SOMATOM Project 10 Emotion CT scanner (K991764). No modifications have been made to the CT scanner that would affect its performance. The gantry tilt and related functionality have been disabled and minor cosmetic changes have been applied.

The software for the ECAT PET/CT is an integration of the PET (PET/*syngo*) and CT (Somaris 5) operating systems on the Siemens *syngo* platform. Operating in a *syngo*-based, NT environment, the ECAT PET/CT operating software provides acquisition, display, diagnostic, application, system, archival, and retrieval support capabilities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2000

William Skremsmky
Regulatory Affairs Specialist
CTI PET Systems, Inc.
810 Innovation Drive
Knoxville, TN 37932

Re: K002715
ECAT PET Scanner
Dated: August 28, 2000
Received: August 31, 2000
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Skremsky:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002715

Device Name: ECAT PET/CT Scanner

Indications for Use:

The CPS/Siemens ECAT PET/CT system is a combined positron emission tomography (PET) and X-ray computed tomography (CT) scanner. The PET/CT scanner is intended to be utilized by appropriately trained health care professionals to 1) image and measure the distribution of injected positron emitting radiopharmaceuticals in humans for the purpose of determining various metabolic and physiologic functions within the human body; and 2) to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002715